

R E M A R K S

Claims 1-6, 8, 10-15 and 21-23 are pending in this application. Claims 7, 9, 16-20 have been canceled. Claims 21-23 have been added and find support in the original claims. All of the present claims are now directed to methods of treatment.

Removal of Objection to Specification

The specification has been objected to for failing to include an Abstract. Consequently, an Abstract has been submitted. Thus, it is requested that this objection be withdrawn.

Removal of Rejection under 35 U.S.C. 101

Claims 1-8, 17 and 18 have been rejected under 35 U.S.C.101 as being directed to non-statutory subject matter, because these claims were originally presented in improper "use" formats. Claims 7, 17 and 18 have been canceled. Claims 1-6 and 8 have been amended so as to recite methods of treatment, which are completely proper under 35 U.S.C.101. Consequently, it is requested that this rejection be withdrawn.

Removal of Rejection under 35 U.S.C.112

Claims 9-16, 19 and 20 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for the reasons (a) - (d) stated at page 3 of the Office Action. It is noted that claims 9, 16, 19 and 20 have been canceled. Remaining pending claims 10-15 have been amended such that these claims all properly depend from amended claim 1. It is submitted that all of the presently pending claims comply with all requirements under 35 U.S.C.112, such that the above-noted rejection should be withdrawn.

Removal of Rejections under 35 U.S.C. 102(b) and 103(a)

Claims 9-16, 19 and 20 have been rejected under 35 U.S.C.102 (b) as being anticipated by either by Calverley '475 (WO/91/15475) or Calverley '629 (U.S. Patent 5,374,629, which corresponds to Calverley '475). These claims have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Calverley '475 and Calverley '629.

It is noted that claims 9, 16, 19 and 20 have been canceled. All of the above-noted rejections are traversed for the following reasons.

Distinctions between Present Invention and Cited Prior Art

All of the presently pending claims are directed to methods of treatment and prophylaxis of osteoporosis and related bone conditions, which include administration to a patient in need thereof an effective amount of a compound of formula I or Ia.

Calverley '475 and Calverley '629 disclose vitamin D analogues, which exhibit anti-inflammatory and immunomodulating effects as well as activity in inducing differentiation and inhibiting undesired proliferation of certain cells, including cancer cells and skin cells. Specifically, Calverley '475 discloses at the first paragraph on page 1 that,

"This invention relates to a hitherto unknown class of compounds which shows anti-inflammatory and immunomodulating effects as well as strong activity in inducing differentiation and inhibiting undesirable proliferation of certain cells, including cancer cells and skin cells, to pharmaceutical preparations containing these compounds, to dosage units of such preparations, and to their use in the treatment and prophylaxis of hyperparathyroidism and a number of disease states including diabetes mellitus, hypertension, acne, alopecia, skin ageing, imbalance in the immune system, inflammatory diseases such as rheumatoid arthritis and asthma as well as diseases characterized by abnormal cell differentiation and/or cell proliferation such as e.g. psoriasis and cancer".

Calverley '629 discloses the same description at column 1, lines 4-18 thereof.

Calverley '475 and '629 fail to disclose or suggest a method for the treatment and prophylaxis of osteoporosis and related bone conditions, which includes administering to a patient in need thereof an effective amount of a compound of formula I or Ia, as in the present invention. The descriptions of possible uses for the compounds disclosed by Calverley '475 and '629 do not mention osteoporosis. Consequently, a person of ordinary skill in the art has no reasonable basis to employ the compounds of the present invention in a method for treating osteoporosis. Therefore, significant patentable distinctions exist between the present invention and the Calverley '475 and Calverley '629 documents.

It is submitted for the reasons stated above, that all of the outstanding issues have been resolved in connection with this application, such that this application should now proceed towards allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Andrew D. Meikle (Reg. No.32,868) at the telephone number of the undersigned below.

Appl. No. 09/787,548

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By 

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